Translation

PATENT COOPERATION TREATY

PCT/FR2003/002384

Rec'd PCT/PTO 25 JAN 2005

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FLAMEL 75	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR2003/002384	International filing date (*day/month/year*) 28 juillet 2003 (28.07.2003)	Priority date (*day/month/year*) 26 juillet 2002 (26.07.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/50		
Applicant FLAMEL TECHNOLOGIES		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23 février 2004 (23.02.2004)	15 December 2004 (15.12.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/002384

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☒ the description:

pages 1-16, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages 1-13, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR 03/02384

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-13	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

D1: FR2670112 A, which describes substrates/cores coated with a mixture of insoluble polymers, soluble polymers (cellulose, pva or pvp derivatives), plasticizers and surfactants;

D2: EP0709087 A, which describes preparations with the same ingredients as the present application (cf. a preparation of acyclovir, for example);

D3: WO0239984 A, where the same composition is obtained for metformine;

D4: US4748023 A, which describes a tablet having high active principle content, consisting of microcapsules coated with a release-retarding polymer, admixed with a soluble polymer which, by swelling in water, acts as a disintegrating agent;

D5: US4321253 A, which describes bacampicillin microcapsules with a soluble and insoluble polymer coating;

D6: FR2313915 A, which describes vincamine microcapsules with a double coating.

Unless otherwise indicated, reference is made to the passages cited in the international search report.

The subject matter of claims 1 to 13 appears novel if the disclaimer in claims 1 and 12 is valid. Due to the problems of clarity, it is not in fact clear exactly what is claimed (cf. Box VIII).

However, the inventive step required by PCT Article 33(1) and (3) cannot be acknowledged. In fact, microcapsule compositions having a coating including double polymer, lubricant and surfactant components are known, even with identical ingredients, and a specific composition cannot be considered inventive unless a surprising effect is demonstrated.

Above all, it is not clear in the present application if the exclusion of certain percentages of the components enables a technical effect to be obtained or if it is rather an arbitrary selection in a field already known from D2, for example.

Contrary to the requirements of PCT Article 6, the wording of claims 1 and 12 appears inconcise and unclear because of the exclusion of certain prior art compositions; wording in positive terms would be preferable.

The lack of clarity of the wording is also demonstrated by the fact that, in the description, page 10, third paragraph, an embodiment of the microcapsules according to the invention coincides exactly with the ranges excluded by the disclaimer in claims 1 and 12. Indeed, the scope of the protection sought is not clear.

A further inconsistency between the description and the claims can be seen from the fact that, in the description (e.g. page 6, line 24), the exclusion of the anti-hyperglycaemic agents is optional.